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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/631,213	07/31/2003	Horace W. Furumoto	1498.1021-015	1428

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EXAMINER

FARAH, AHMED M

ART UNIT PAPER NUMBER

3739

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/631,213	Applicant(s) FURUMOTO, HORACE W.	
	Examiner Ahmed M Farah	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>November 10, 2003</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-26 of U.S. Patent No. 6,610,052. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are directed to an apparatus and methods of use for treating a biological tissue with a pulsed laser light comprising a series of sub-pulses having a predetermined periodicity and duty cycle over a selected effective pulse duration.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-13 and 19-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Miller U.S. Patent 6,027,495.

Miller discloses apparatus and method for removal of unwanted leg veins and other vascular lesions from skin of a patient, the method comprising the steps of: generating a long effective output light pulse having a pulse duration in the range of about 20-99 milliseconds; and directing the output light pulse to the tissue being treated (see claim 1 and the abstract).

The output light pulse of Miller comprises a series of sub-pulses having a pulse duration in the range of about 1-3 milliseconds (see Col. 11, lines 11-17 and claims 9-10).

In this Office Action, the term "duty cycle" is treated as *the product of the pulse duration and pulse frequency of a pulse carrier, equal to time per second that pulse power is applied*; and the term "thermal relaxation time" is treated as *the time it takes for body of particular characteristics (shape, material, structure, etc.,) to dissipate 50% of its heat energy*.

Therefore, Miller's sub-pulses (1-3 ms pulse duration) have a fractional duty cycle over the selected effective pulse duration (20-99 ms) of the output light pulse.

As to the limitation that the sub-pulses have "a periodicity that is less than the thermal relaxation of a targeted structure" as in claims 1 and 11, Miller's sub-pulse pulses (1-3 ms pulse duration) have a pulse duration that is less than the thermal relaxation time of most body parts. For example, the skin has a thermal relaxation time of about 10 ms, dermis has a thermal relaxation time of about 60 ms, and hair follicle has a thermal relaxation time of between 20-100 ms, depending the size of the hair follicle.

Further more, as to the recitation in claims 1 and 11 that the "interpulse-delay between successive sub-pulses" is greater than the thermal relaxation time of non-targeted structures, Miller teaches that the pulse repletion rate between the successive sub-pulses is between 1-20 Hz. This clearly indicates that the time between the laser pulse/ sub-pulses is between 50 ms to 1 second. Therefore, a pulse delay of between 50 ms to 1 second is apparently greater than the thermal relaxation time of non-targeted structure, such as skin that has a thermal relaxation time of about 10 ms, dermis has a thermal relaxation time of about 60 ms, and hair follicle has a thermal relaxation time of between 20-100 ms.

As to claims 12 and 13, Miller teaches the use of various laser sources including a dye laser (Col. 2, line 45) and a semiconductor laser (Col. 9, line 7).

As to claims 4, 5, 20, and 21, he discloses that the targeted structure comprises blood vassals that are larger than 30 microns in diameter (Col. 7, lines 26-27).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 14-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eckhouse et al. U.S. Patent 5,964,749.

Although Miller, described above, teaches that the operating wavelength (700-1100 nm) of the source constitutes type of the laser used, he does not particularly teach the use of the a gas discharge laser, an alexandrite laser, a ruby laser, or an Nd:YAG laser as presently claimed.

However, Eckhouse et al. teach an alternative method and apparatus for treating skin conditions wherein the radiation source is selected from the group consisting of a ruby laser, alexandrite laser, Nd:YAG laser, and other suitable coherent light source that operate in the wavelength range of 600-1200 nm. Therefore, it would have been obvious to one skilled in the art at the time of the applicant's invention to modify Miller with Eckhouse et al. and use a ruby laser, alexandrite laser, or an Nd:YAG laser as an alternative light source in order to provide treatment light to a desired tissue. These laser sources operate in the wavelength ranges specified by Miller for his treatment methods.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See the following reference:

U.S. Pat. No. 6,197,020 B1 to O'Donnell, Jr. disclose a laser apparatus for treating biological tissue, comprising: generating a long effective laser light pulses (800-1.79 nm), the pulses comprising a series of sub-pulses having a fractional duty cycle over a selected effective pulse duration and a periodicity that is less than the thermal relaxation time of the targeted structure (Col. 2, lines 54-65); and delivering the light to the tissue of a patient.

In reference to claims 1 and 11 of the instant application, he teaches that the pulse duration is less than 60 ms (see claims 11 and 12). However, the inter-pulse delay of 60 ms seconds is not greater the relaxation time of most structures of the biological tissue as recited in the in claims 1 and 11 of the instant claims.

In reference to claims 14 and 18, his invention employs a gas laser (CO₂) and an Nd:YAG laser (Col. 4, lines 35-38).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ahmed M Farah whose telephone number is (703) 305-5787. The examiner can normally be reached on Mon-Thur. 9:30 AM-7:30 PM, and 9:30 AM - 6:30 PM on every other Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M DVorak can be reached on (703) 308-0994. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A. Farah,

Patent Examiner, AU 3739



05/16/2004.